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Valsartan_ Monthly Status Report 11 Jan 16 2020.pdf

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16 2020.pdf



January 16, 2020

LCDR Dellarese Herbert
Division of Pharmaceutical Quality Operations 1
900 US Customhouse Suite 904
Philadelphia, PA 19106

RE: Valsartan-containing Products

Mylan Pharmaceuticals Inc and Mylan Laboratories Limited, Nashik and Aurangabad
API Manufactured by Mylan Laboratories Limited, Unit 8

Class II Recall to Consumer Level
FDA Recall Number D-0311-2019 to D-0318-2019

Dear LCDR Herbert,

Enclosed, please find the monthly status report for Mylan Pharmaceuticals Inc. recall of the above referenced products. Mylan Pharmaceuticals Inc is utilizing Stericycle services for distribution of the recall notification packet, product return, tracking and destruction of the affected product.

1. Number of consignees notified of recall, date and method of notification:

A total of 139 direct consignees were notified by the recall notification packet on November 21, 2018 and by the expanded recall notification packet on December 04, 2018. The recall notification packet consisted of the Recall Notification Letter, a Business Reply Card (BRC), a Packing Slip and a prepaid Return Label.

To date, there are 22,655 consignee additions for a total of 22,794 wholesale and retail level consignees.

To date, there are 6,916 consumer level consignees.

2. Number of consignees responding to the recall notification letter:

Wholesale

To date, there are 110 out of 139 consignees that have responded to the recall notification letter.

Retail

To date, there are 8,660 out of 22,655 consignees that have responded to the recall notification letter.

Consumer

To date, there are 5,213 out of 6,916 consignees that have responded to the recall notification letter.

3. Number of consignees that did not respond to the recall notification letter:

Wholesale

To date, there are 29 out of 139 consignees that have not responded to the recall notification letter.

Retail

To date, there are 13,995 out of 22,655 consignees that have not responded to the recall notification letter.

Consumer

To date, there are 1,703 out of 6,916 consignees that have not responded to the recall notification letter.

4. *Quantity of returned product:*

Wholesale

To date, there are 121,936 bottles and 621 partials returned, representing 140,908 tablets.

Retail

To date, there are 183,848 bottles and 40,267 partials returned, representing 1,930,970 tablets.

Consumer

To date, there are 406 bottles and 2,464 partials returned, representing 149,356 tablets.

5. *Number and results of effectiveness checks that were made:*

Effectiveness checks were conducted in July 2019. There were 31 required checks. There were 10 consignees that were unresponsive, 10 consignees that were unable to be contacted, 3 consignees were uncooperative and 8 checks were completed.

6. *Estimated time frames for completion of the recall*

Mylan will not request destruction at this time, and request product to be held in quarantine at Stericycle pending a legal hold due to on-going litigation.

If you have any questions or require additional information, please do not hesitate to contact me at (304) 554-6614 or at Cassandra.bird@mylan.com.

Sincerely,

Cassandra Bird

Cassandra M. Bird
Recall Coordinator
Global Quality Operations

Cc: Vinay Bhatt
Head of OSD Quality, Morgantown

Cc: Misty Quince
Director, NA Quality